

Exhibit A

Do Not Disclose - Subject to Further Confidentiality Review

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

No. MD-15-02641-PHX-DGC

IN RE BARD IVC FILTERS PRODUCTS

LIABILITY LITIGATION

DO NOT DISCLOSE

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CLEMENT J. GRASSI, MD

Thursday, June 15, 2017

9:24 a.m.

Held At:

Nelson Mullins Riley & Scarborough LLP

One Post Office Square

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

1 and I have to try to think back over years of
2 working with them, I have not retrieved a Bard
3 recent device where I've seen a fracture, no.

4 THE VIDEOGRAPHER: Dr. Grassi, I'm
5 getting some noise from the wire.

6 THE WITNESS: Sorry about that. Is
7 that better?

8 THE VIDEOGRAPHER: That's great. It's
9 just if you --

10 THE WITNESS: Thank you. Thanks for
11 letting me know.

12 BY MR. ROTMAN:

13 Q. Have you ever implanted a Bard
14 Recovery filter?

15 A. In the past, no, I don't believe I've
16 used the Recovery personally.

17 Q. Have you ever implanted a Bard G2
18 filter?

19 A. Yes.

20 Q. How many?

21 A. I would have to only estimate. I
22 would say ten to a dozen.

23 Q. And have you ever retrieved a Bard
24 Recovery filter?

1 A. Yes. And perhaps one-third of the
2 previous number?

3 Q. So the number would be what?

4 A. Say three to four filters, from
5 memory.

6 Q. So you've retrieved about three
7 Recoveries in your career?

8 A. Again, this would be based on memory
9 from years back.

10 Q. You've implanted no Recoveries, and
11 retrieved approximately three, from your memory,
12 from years back, correct?

13 A. Well, I think you asked the question
14 of me, if I'm correct, about G2 filters, is that
15 true?

16 Q. Let's just make it clear since there's
17 some confusion. Let's just talk about Recovery
18 for now.

19 A. Okay.

20 Q. You've never implanted a Recovery
21 filter, correct?

22 A. From memory, I don't remember
23 Recovery. And I don't remember having retrieved
24 a Recovery.

1 Q. Okay. So now let's go to the G2.

2 Have you implanted a G2; and if so,
3 how many?

4 A. Yes. And again, it would be by memory
5 an estimate. A dozen or more.

6 Q. And how many have you retrieved, if
7 any?

8 A. By memory, four filters or more.

9 Q. And have you seen any fractures in any
10 of the patients where you've either implanted or
11 retrieved a G2?

12 MR. BROWN: Object to the form. Asked
13 and answered.

14 A. I believe I answered that question.
15 From memory, I don't remember having seen that.
16 BY MR. ROTMAN:

17 Q. And I understand you've never seen a
18 fracture of a Bard Recovery filter in your own
19 patients -- sorry. Strike that.

20 You have seen Recovery fractures from
21 patients of other physicians in your hospital?

22 A. Well, of colleagues in general.

23 Q. Colleagues.

24 How many?

1 A. From memory, over the years, I can say
2 that perhaps one or two cases were shown as
3 examples by colleagues.

4 Q. Other than fracture, do you consider
5 tilt to be a complication?

6 A. I consider tilt to be one aspect of
7 many types of vena cava filters.

8 Q. I'm asking if you consider a tilt of
9 any filter to be a complication.

10 A. I do not consider it to be a
11 complication unless there is an adverse event
12 with symptoms or signs in that particular
13 patient.

14 Q. And do you consider a perforation to
15 be a complication of an IVC filter?

16 A. A perforation, if it is of a moderate
17 to severe nature, and where there are either
18 adverse symptoms or signs in that patient would
19 be considered a complication.

20 Q. So if there's no symptoms or signs in
21 conjunction with a moderate to severe
22 perforation, you do not consider that to be a
23 complication of the filter?

24 A. I would say that specifically and in

1 the literature, penetration that is 3
2 millimeters or less is usually defined as
3 different from perforation greater than 3
4 millimeters. So that if there were to be, for
5 example, a moderate perforation but the patient
6 had no adverse events, had no symptoms, we could
7 say that that was an image-identified
8 complication, but was not, obviously, a
9 symptomatic complication for that patient
10 because they had no adverse outcome.

11 Q. But you would consider it to be a
12 complication of the device?

13 MR. BROWN: Object to form.

14 A. We could put it into that category,
15 yes.

16 BY MR. ROTMAN:

17 Q. If it's a moderate to severe
18 perforation without symptoms?

19 A. Correct, as compared to the more minor
20 degree of a penetration.

21 Q. And have you ever seen a perforation
22 of a Bard recovery filter?

23 A. I've seen them in cases, and displayed
24 at medical meetings, and talked about with

1 colleagues.

2 Q. How many perforations of Bard Recovery
3 filters have you seen?

4 A. Overall in the whole group?

5 Q. Bard Recovery.

6 A. Yes, in your question, Counselor, so
7 that I can understand --

8 Q. How many Bard Recovery filter
9 perforations have you seen?

10 A. When you say when I've seen, I assume
11 you mean overall. And I would say that at
12 scientific meetings, with colleagues, and just
13 from practice experience, I have had a chance to
14 see, that is see described, approximately five
15 to six perforations.

16 Q. And how many in your own patients?

17 A. In my own patients, I remember one.

18 Q. So now we've got, I want to talk about
19 -- do you consider a tilt without symptoms to be
20 a complication of the device?

21 A. I do not consider that to be a
22 complication because, as you know, tilt can be
23 shown both in Bard devices and in other IVC
24 filters, and may be of no clinical significance

1 for the patient.

2 Q. Well, that same explanation would
3 apply to a fracture, correct?

4 A. It would if the fracture were
5 identified by imaging alone, and the patient had
6 no signs and no symptoms.

7 Q. So if you -- you would not consider
8 that to be a complication of the device?

9 MR. BROWN: Object to the form.

10 A. To be fair to your question, I would
11 consider that to be a complication which has
12 been identified by imaging.

13 BY MR. ROTMAN:

14 Q. Yes.

15 And so, have you ever seen a Bard
16 Recovery tilt complication?

17 MR. BROWN: Object to the form.

18 A. I have seen Bard Recovery filter
19 tilting, yes.

20 BY MR. ROTMAN:

21 Q. How many times?

22 A. I would estimate approximately three
23 times.

24 Q. Have you ever implanted a Bard G2X?

1 A. To be fair to your question, I would
2 actually have to look back to records, because I
3 don't hold that in memory, whether the
4 particular filter was a G2X or a G2. And I
5 would say that I really can't give you, to be
6 fair, I can't give you an accurate answer to
7 that question at this moment.

8 Q. Have you ever retrieved a G2X?

9 A. Really, the same answer to that.

10 Q. Have you ever implanted a Bard
11 Eclipse?

12 A. Yes.

13 Q. How many?

14 A. For that filter, which is a more
15 modern device, I would estimate 50 or more.

16 Q. About how many filters do you implant
17 in a given year?

18 A. The number of filters will vary per
19 year, as it does per month. For myself, it
20 might be between 30 and 40 devices in a year,
21 depending on the particular year.

22 Q. And that would be all filters, all
23 manufacturers combined?

24 A. That's correct, all types.

1 Q. Do you know what period of time the
2 Eclipse was on the market?

3 A. The Eclipse was on the market in the
4 period around 2008 to 2009, and I could not give
5 you an exact date range.

6 Q. Do you know what period of time, you
7 know, whether it was a year or two years,
8 three years, that the Eclipse was on the market?

9 A. Well, the Eclipse was not on the
10 market, as I understand it, for a long period of
11 time because there was the next iteration, the
12 Meridian, that was introduced by Bard, and that
13 filter was the device that we had subsequently
14 used.

15 Q. So the answer to my question is? Was
16 it one years, two years, three years, do you
17 know?

18 A. For the Eclipse?

19 Q. Yes.

20 A. My impression from memory is that the
21 Eclipse was in clinical use between a year and
22 two years, as an estimate.

23 Q. In that one to two years where you
24 would have implanted 30 to 40 filters of all

1 manufacturer types per year, you implanted 50 or
2 more Eclipse devices?

3 MR. BROWN: Object to the form.

4 A. I'm sorry, I don't understand your
5 question.

6 MR. ROTMAN: Could you reread it,
7 please?

8 (Whereupon, the reporter read back the
9 pending question.)

10 MR. BROWN: Same objection.

11 A. Well, I think that we're having a
12 misunderstanding on the wording of the question.
13 So when you had asked me how many Eclipse
14 devices have you implanted, I gave you from
15 memory an estimate number. Okay. And the exact
16 number, to be fair, I would have to go back and
17 check records.

18 BY MR. ROTMAN:

19 Q. Your estimate was 50. I didn't
20 misstate that, right? That was what you
21 testified as your estimate, right?

22 A. That was my approximation.

23 Q. And how many Eclipses have you
24 retrieved?

1 A. Again, from memory as an
2 approximation, eight or more filters.

3 Q. And have you ever had a patient with
4 an Eclipse complication?

5 MR. BROWN: Object to the form.

6 A. Personally, no.

7 BY MR. ROTMAN:

8 Q. And have you ever implanted a
9 Meridian?

10 A. By memory, and to the best of my
11 recollection, yes.

12 Q. Approximately how many?

13 A. Again, the exact number would be
14 something I would have to check records. I
15 would say, as an estimate, 20 or more devices.

16 Q. What records would you be able to
17 check to give you the information about the
18 number of Meridians that you've implanted?

19 A. Well, that would be challenging,
20 because one would have to go back to either
21 medical records, specific patient records, or
22 perhaps even consult the company if there were a
23 product use invoice slip sent.

24 Q. How many Meridians have you retrieved?

1 A. Again, as an estimate, six or more
2 devices.

3 Q. And have you ever seen a Meridian
4 complication among your own patients?

5 MR. BROWN: Object to the form.

6 A. Personally, let's see, yes, I've seen
7 a case in which in my own patients there was not
8 a complication but there was, due to the
9 indication for use in the superior vena cava,
10 the arm processes not being in standard position
11 within the vena cava.

12 BY MR. ROTMAN:

13 Q. Do you consider that to be a
14 complication of the device?

15 MR. BROWN: Object to the form.

16 A. No, simply because the patient had
17 severe embolus within the SVC, and was in a
18 state where she might have died within the next
19 two to four hours, and so the filter actually
20 was lifesaving.

21 BY MR. ROTMAN:

22 Q. Have you ever implanted a Denali?

23 A. Yes.

24 Q. How many?

1 A. Again, as an estimate, 50 or more
2 devices.

3 Q. And have you ever retrieved a Denali?

4 A. Yes. And I would say the estimate
5 there would be six or more devices.

6 Q. And have you ever seen a Denali
7 complication?

8 MR. BROWN: Object to the form.

9 A. Personally, no.

10 BY MR. ROTMAN:

11 Q. Have you ever conducted a study of the
12 patients in any of the hospitals where you
13 worked to assess the complications in IVC
14 retrievable filters in those patient
15 populations?

16 A. I've participated in studies with IVC
17 permanent filters, but not retrievable ones.

18 Q. And have you ever proposed a study of
19 retrievable filters in any of the hospitals in
20 which you have been a staff radiologist to
21 assess the status of the filters implanted in
22 the patients in that institution?

23 MR. BROWN: Object to the form.

24 A. By the question, study, you're

1 Q. Are there any standards that you
2 followed for making that assessment?

3 A. In terms of looking at filters
4 overall, I get help from the guidelines
5 published by Society of Interventional
6 Radiology.

7 Q. Anything else?

8 A. Well, also literature and commentary
9 from the ACR, that is American College of
10 Radiology, in their publications.

11 Q. What standards did you use for
12 weighing the evidence that you were evaluating?

13 A. I try to look at the evidence that is
14 in the published literature according to the
15 categories, that is whether the information is
16 more reliable in various grades to less
17 reliable.

18 For example, single case reports,
19 letters to the editor, anecdotal reports would
20 be considered lower levels of evidence. Single
21 center studies in hospitals would be considered
22 moderate. Multicenter studies would be
23 considered moderate to high. And any study
24 which would be a randomized prospective

1 multicenter trial would be the highest level of
2 evidence as described in our literature and per
3 our scientific committees, which would be
4 considered more level 1 evidence.

5 Q. If you were interested in determining
6 whether a patient who had an implanted Bard
7 retrievable IVC filter had any -- had a fracture
8 of that filter, what would be the best way for
9 you to make that determination?

10 A. My own practice would be to image the
11 patient either with plain film, fluoroscopy, or
12 a CT scan possibly.

13 Q. And what would be the advantages of an
14 abdominal non-contrast CT scan over other
15 options?

16 A. Well, an abdominal non-contrast CT
17 scan would, by the nature of the technology,
18 create a 3D representation of the device. One
19 could look at it not only in one plane, as would
20 be the case with an abdominal radiograph, but
21 reconstruct the image, and use window and
22 leveling techniques to assist with determination
23 if there's a fracture of the device.

24 Q. Do you ever use -- or do you ever

1 reproduce the same problem. That kind of proof
2 for social and human and psychological reasons
3 obviously is fraught with problems, because one
4 would not want to take a defective device and
5 introduce it into one of our brothers or sisters
6 and create a problem in order to provide proof.

7 I would say that the type of proof
8 that I look for is a convincing explanation
9 where the scientific researcher identifies a
10 problem, can show how and why it occurs, and
11 then can demonstrate a very consistent pattern
12 where the problem can be explained by the exact
13 theory that he or she is proposing.

14 Q. You used the word "convincing." What
15 does convincing mean?

16 A. Where there is really reliable and
17 sound medical evidence behind it.

18 Q. Such that you would be -- to what
19 level of certainty would you require for there
20 to be convincing evidence?

21 A. I would say that in general, as I
22 answered before, if one can identify a problem,
23 define what the mechanism is, show a consistent
24 pattern in animals, in human, and provide really

1 reproducible sound examples that show where that
2 has occurred, those would be the factors that as
3 a practicing physician I would look for.

4 MR. ROTMAN: I'm going to move to
5 strike as non-responsive.

6 Q. I'm asking a very specific question
7 about what level of certainty you require for
8 something to meet the convincing standard that
9 you're -- that you've referenced in your prior
10 answer. So when I ask that question, what I
11 mean is, 100 percent certain, 95 percent
12 certain, more likely than not certain, possibly,
13 probably, highly likely, these are all levels of
14 -- ways to describe levels of certainty.

15 What level of certainty do you use in
16 connection with your standard of looking for
17 convincing evidence?

18 MR. BROWN: Object to the form. Asked
19 and answered.

20 A. Well, I believe I've answered that,
21 but I'll try your question again.

22 BY MR. ROTMAN:

23 Q. I gave you various options. Do any of
24 those fit?